



August 3, 2021

VIA CM/ECF

Honorable Thomas J. Vanaskie, Special Master
Stevens & Lee, P.C.
1500 Market Street, East Tower, 18th Floor
Philadelphia, Pennsylvania 19103

Re: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*,
No. 1:19-md-02875-RBK-JS (D.N.J.)

Dear Judge Vanaskie:

Plaintiffs respectfully submit this letter relating to their challenges to certain privilege claims asserted by Hetero Drugs, Ltd. and Hetero Labs, Ltd. (collectively referred to as “Hetero”), pursuant to the discussion at the July 28, 2021 conference. Based on the information set forth in the privilege log (“Log”), Plaintiffs have grouped their challenges into seven categories and provided the specific documents challenged in each category as well as a brief rationale below for the Court’s reference.

1. Communications With Outside Consultants Are Not Privileged

Hetero asserts that communications between its employees, consultants hired by Hetero and outside counsel are privileged (See Log numbers 40, 45, 113, 216, 219, 220, 231, 300, 322 and 399). Similarly, Hetero claims that communications between its employees and consultants are privileged (See Log numbers 3, 6, 40, 216, 219 and 220). Finally, Hetero claims that communications between its lawyers and its consultants are privileged (See Log numbers 47, 56, 61, 216, 219, 231).

Hetero’s Cast of Characters identified Elyse Smith as an “outside consultant” who works for Meridan Consulting (“Meridan”). Elyse Smith is the President of Meridan and is identified on

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Log numbers 3, 6, 216, 219, 220, 231 and 399. According to its website, Meridian is a global regulatory compliance consulting firm for FDA-regulated industries, is operated by a former US FDA investigator, and its team is uniquely qualified to assess facilities, file product applications and provide specific direction to facilitate a successful inspection outcome. (See www.meridianconsulting.com last visited 08/2/21) .

Hetero's Cast of Characters identified Myriam M. Sosa as an "LLC-GMP consultant" who works for the Gintegra Group. Ms. Sosa is identified on Log number 322. Upon information and belief, Ms. Sosa is a compliance and regulatory professional and former FDA employee.

Hetero identified Ali Afnan as "President" of Step Change Pharma, Inc. on its Cast of Characters. Mr. Afnan is identified on Log numbers 40 and 113. Upon information and belief, Step Change Pharma provides consulting services to the pharmaceutical industry.

Finally, Hetero identified Anthony Alonzo Charity as a "Representative" from Step Change Pharma, Inc. Mr. Charity received the communication identified on Log number 40.

Communications with a third-party consultant may result in the loss of confidentiality and the privilege then ceases to protect them. Disclosure is conclusive evidence the client does not wish the communication to remain confidential. Likewise, documents that were forwarded to various Hetero employees lose any privilege that may otherwise have applied because there is no continued expectation that the communication remains confidential (See Log numbers 6, 31, 32, 40, 45, 216, 219, 220, 231, 269, 300 and 399).

2. Routine Business Communications and Communications Involving Mixed Business Information are Not Privileged

It appears that the documents identified as Log numbers 3, 6, 31, 32, 40, 45, 47, 56, 61, 113, 216, 219, 220, 231, 269, 300, 322 and 399 (and maybe others) fall in this category and should be produced. Communications between employees or third parties, including consultants, that

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involve routine business communications are not privileged. *In re Riddell Concussion Reduction Lit.* (D. N.J. 2016). It is well known that the FDA investigates pharmaceutical companies regularly and an investigation of a facility certainly does not mean that litigation will ensue. However, it is highly probable that such an investigation results in many communications by a pharmaceutical company that would be considered for routine business purposes or that involve mixed business information. The communications with the consultants appear to involve the FDA's actions relating to the contamination of Hetero's prescription medications. This involves a business issue and does not involve litigation or potential litigation.

3. Statements of Fact are Discoverable

Statements of fact are not privileged from disclosure. The following descriptions in the privilege log indicate a likelihood that facts were disclosed in several of the Challenged Documents. For example, see Log number 1 ("providing information to facilitate counsel's legal advice") and Log numbers 3 and 6 ("providing information to facilitate counsel's legal advice regarding March 13, 2019 meeting with FDA"). It is likely that the documents set forth statements of fact. Similarly, Log numbers 20, 31, 32, 56, 61, 216, 219, 220, 231, 300, 322 and 399 all appear to include statements of fact. Hetero should be compelled to produce all statements of fact in the Challenged Documents.

4. Merely Copying Counsel on a Communication Does Not Make it Privileged

Hetero wrongfully maintains that communications copied to counsel are privileged even though it does not appear legal advice was sought or given (See Log numbers 6, 113, 216, 219, 220, 231, 269 and 399). Routine, non-privileged communications do not become privileged simply because the author copied a lawyer on the communication and Hetero should be ordered to produce them.

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5. Communications That Do Not Involve Attorneys are not Privileged

No privilege attaches to communications that do not involve attorneys. No attorneys were involved in an email chain forwarded by Hetero employee Gouda to co-employee Vundyala and supposedly providing counsel's legal advice regarding a draft supplemental submission to the FDA concerning an inspection report and a phone call on April 4, 2017 with the FDA (See Log number 45). As a result, no privilege attaches to such communications and Hetero should be ordered to produce it.

6. Hetero's Work Product Privilege Claims Fail

Hetero also wrongfully asserts that the work product doctrine applies to documents identified on Log numbers 20, 32 and 399. As an initial matter, Hetero failed to assert the work product doctrine regarding Log numbers 32 or 399 in its original privilege log dated December 17, 2020 and did not claim that Log numbers 32 and 399 were protected by the work product doctrine until it served another privilege log nearly six months later, on May 5, 2021. Under these circumstances, Hetero has waived any claim that Log numbers 32 and 399 are protected by the work product doctrine. *Ritacca v. Abbot Laboratories*, 203 F.R.D. 332, 336 (N.D. Ill. 2001). However, even if the court determines that Hetero did not waive the work doctrine privilege relating to those documents, they are not protected from disclosure for other reasons.

The work product doctrine only protects from disclosure material prepared in anticipation of, and because of, the prospect of litigation or trial. However, materials prepared in the ordinary course of business or pursuant to regulatory requirements or for other non-litigation purposes are not documents prepared in anticipation of litigation or trial.

The Log identifies the file name for Log number 20 as "Q & a from Hetero USA 7 10 2019" and identifies Hetero employee Venkata M. Ramana as the author. The description for

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Log number 20 is “Draft memorandum prepared at the request of counsel in connection with pending Valsartan litigation.” However, there is no request by counsel identified to which this would be responsive, and to the extent the document contains facts rather than analysis, the document should, at the very least, be produced in redacted form.

Log number 32 is identified as an email from Hetero employee Dr. Venkataramana Madireddy to Hetero employee Dr. Manoranjan Kumar and copying SuryaGopala Krishna Tummuri. It is described as an “Email providing counsel’s legal advice regarding draft submission to FDA concerning request for desk review lieu of on-site inspection by FDA.” Furthermore, the Log indicates that there is an attachment to the email. This information fails to satisfy Hetero’s burden to prove that the work product doctrine applies to the document and it should be produced.

Log number 399 describes a “Draft memorandum prepared by HLL’s consultant providing information to Hogan Lovells to facilitate counsel’s legal advice regarding meeting with FDA”. The description for Log number 399 supports a finding that it is not protected from disclosure by the work product doctrine. Rather, it appears to have been prepared in the ordinary course of business pursuant to regulatory requirements or for other non-litigation purposes. For these reasons, Hetero’s work product claims should be overruled and it should produce the documents.

7. Failure to Assert Any Privilege Results in Waiver

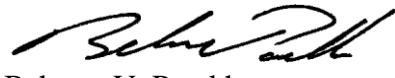
Finally, Hetero failed to assert any privilege with respect to Log numbers 210, 310 and 389. As a result, any privilege claim has been waived and it should be ordered to produce the documents.

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Conclusion

Plaintiffs respectfully request an order denying Hetero's privilege claims, requiring it to produce the documents referenced herein within 7 days of the order and that Hetero de-designate all similar documents and produce them to Plaintiffs by a date certain.

Respectfully submitted,



Behram V. Parekh

cc: All Counsel (via CM/ECF)